

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

In re Sitagliptin Phosphate ('708 & '921)
Patent Litigation

C.A. No. 19-md-2902-RGA

MERCK SHARP & DOHME CORP.,

Plaintiff,

v.

TORRENT PHARMACEUTICALS
LIMITED, and TORRENT PHARMA, INC.,

Defendants.

C.A. No. 19-872-RGA

**ANSWER TO COUNTERCLAIMS OF
TORRENT PHARMACEUTICALS LIMITED and TORRENT PHARMA, INC.**

Plaintiff and Counterclaim Defendant Merck Sharp & Dohme Corp. (“Merck”), by its attorneys, hereby answers the counterclaims of Defendants and Counterclaim Plaintiffs Torrent Pharmaceuticals Limited (“Torrent Ltd.”) and Torrent Pharma, Inc. (“Torrent Pharma,” collectively, “Torrent”).

COUNTERCLAIMS

1. On information and belief, Merck admits the allegations of Paragraph 1.
2. On information and belief, Merck admits the allegations of Paragraph 2.
3. Merck admits the allegations of Paragraph 3.

Jurisdiction and Venue

4. The allegations of Paragraph 4 set forth legal conclusions to which no response is required. To the extent an answer is required, Merck does not contest that this Court has subject matter jurisdiction over this action.

5. The allegations of Paragraph 5 set forth legal conclusions to which no response is required. To the extent a response is required, Merck does not contest personal jurisdiction for the purposes of this action only.

6. The allegations of Paragraph 6 set forth legal conclusions to which no response is required. To the extent a response is required, Merck admits that this Court is a proper venue for this action.

The Controversy

7. Merck admits that in a letter dated May 2, 2019 (“Torrent’s ’153 Notice Letter”), Torrent notified Merck that it had submitted ANDA No. 213153 to the FDA seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, and/or importation of generic sitagliptin phosphate and metformin hydrochloride oral tablets (“Torrent’s ’153 ANDA Product”) prior to the expiration of U.S. Patent No. 7,326,708 (“the ’708 patent”). Merck otherwise lacks sufficient information and knowledge to form a belief as to the truth of the allegations in of Paragraph 7.

8. Merck admits that it filed a complaint against Torrent on May 9, 2019 and respectfully refers the Court to the Complaint for its actual language and complete content. Merck admits that there is an actual case of controversy between Merck on the one hand and Torrent on the other regarding Torrent’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’708 patent. Merck denies any remaining allegations in Paragraph 8.

9. The allegations of Paragraph 9 set forth legal conclusions to which no response is required. To the extent a response is required, Merck admits that there is an actual case of controversy between Merck on the one hand and Torrent on the other regarding Torrent's infringement, active inducement of infringement, and contribution to the infringement by others of the '708 patent.

COUNT I
Declaratory Judgment of Invalidity of the '708 Patent

10. Merck incorporates by reference Paragraphs 1–9 as though fully set forth herein.

11. Merck denies the allegations of Paragraph 11.

COUNT II
Declaratory Judgment of Non-Infringement of the '708 Patent

12. Merck incorporates by reference Paragraphs 1–11 as though fully set forth herein.

13. Merck denies the allegations of Paragraph 13.

Response to Demand for Judgment

The “WHEREFORE” paragraphs following Paragraph 13 set forth the remainder of Torrent's request for relief, to which no response is required. To the extent that a response is required, Merck denies the allegations in the “WHEREFORE” paragraphs following Paragraph 13 and denies that Torrent is entitled to its requested relief, or any relief whatsoever.

To the extent that a further answer is required to any paragraph of Torrent's counterclaims, Merck denies all further allegations. Any allegation of Torrent's counterclaims not expressly admitted herein is hereby denied.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

Torrent's counterclaims fail to allege facts sufficient to state a cause of action and fail to state a claim on which relief may be granted.

SECOND AFFIRMATIVE DEFENSE
(Statutory Bar)

Some or all of the relief requested by Torrent's counterclaims is barred by 21 U.S.C. § 355(j) *et seq.*

Merck reserves the right to assert further affirmative defenses in the event that discovery indicates that such defenses would be appropriate.

PRAYER FOR RELIEF

WHEREFORE, Merck requests the following relief:

- (a) An order dismissing each of Torrent's counterclaims, with prejudice, and denying all relief sought by Torrent;
- (b) A declaration that this is an exceptional case and an award of attorney's fees pursuant to 35 U.S.C. § 285;
- (c) Costs and expenses in this action; and
- (d) Such further and other relief as this Court may deem just and proper.

Dated: August 26, 2019

Respectfully submitted,

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

Michael P. Kelly (#2295)

Daniel M. Silver (#4758)

Alexandra M. Joyce (#6423)

Renaissance Centre

405 N. King Street, 8th Floor

Wilmington, DE 19801

T: (302) 984-6300

mkelly@mccarter.com

dsilver@mccarter.com

ajoyce@mccarter.com

Attorneys for Plaintiff

Merck Sharp & Dohme Corp.

OF COUNSEL:

Bruce R. Genderson

Jessamyn S. Berniker

Stanley E. Fisher

Alexander S. Zolan

Shaun P. Mahaffy

Anthony H. Sheh

Jingyuan Luo*

WILLIAMS & CONNOLLY LLP

725 Twelfth Street, N.W.

Washington, DC 20005

T: (202) 434-5000

F: (202) 434-5029

bgenderson@wc.com

jberniker@wc.com

sfisher@wc.com

azolan@wc.com

smahaffy@wc.com

asheh@wc.com

jluo@wc.com

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Rule 49(c)(8).*